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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/892,085	06/26/2001	Ulrich Laemmli	0857/62479-A/JPW/GJG	9903

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EXAMINER	
PRIEBE, SCOTT DAVID	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/892,085	LAEMMLI, ULRICH	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 17/15, and 19 (as directed to *in vitro*), drawn to a method for modulating the function of a DNA element in a eukaryotic cell *in vitro* by treatment with a polymer comprising heterocyclic monomers that binds an endogenous CRE in a sequence-specific manner, which binding alters the activity of an other endogenous DNA element, classified in class 435, subclass 375.

II. Claims 17/15, and 19 (as directed to *in vivo*), drawn to a method for modulating the function of a DNA element in a eukaryotic cell *in vivo* by treatment with a polymer comprising heterocyclic monomers that binds an endogenous CRE in a sequence-specific manner, which binding alters the activity of an other endogenous DNA element, classified in class 424, subclass 78.32.

III. Claims 17/16, 18 and 19 (as directed to *in vitro*), drawn to a method for modulating the function of a DNA element in a recombinant eukaryotic cell *in vitro* by treatment with a polymer comprising heterocyclic monomers that binds a CRE in a sequence-specific manner, which binding alters the activity of an other DNA element, wherein the CRE or other DNA element or both are heterologous to the cell, classified in class 435, subclass 455.

IV. Claims 17/16, 18 and 19 (as directed to *in vivo*), drawn to a method for modulating the function of a DNA element in a recombinant eukaryotic cell *in*

vivo by treatment with a polymer comprising heterocyclic monomers that binds a CRE in a sequence-specific manner, which binding alters the activity of an other DNA element, wherein the CRE or other DNA element or both are heterologous to the cell, classified in class 514, subclass 44 or class 800, subclass 3.

Note: Claim 17 is a multiple dependent claim, and the designations 17/15 and 17/16 refer to the embodiments of claim 17 dependent from claims 15 and 16, respectively. As used above, cell *in vitro* includes unicellular eukaryotes, e.g. yeast, and cell *in vivo* means a cell in a multicellular eukaryote. If either of inventions III or IV is elected, claim 39 will be examined.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not taught as being used together. In each invention, the function and effects are different, i.e. each is practiced on different products, cultured recombinant or non-recombinant cells, or recombinant or non-recombinant cells in plants or animals and the goal of the method depends upon the specific cell on which the method is practiced. For example, whereas the goal in treating a non-recombinant cell with the polymer would be to effect an epigenetic change on a naturally-occurring cell or organism, the goal with recombinant cells appears to be regulating expression of an exogenous target gene, such as in a vector. The separate classification of these different inventions shows that they have attained separate status in the art, and would require

different searches. The issues for examination, e.g. enablement, would also be different, particularly between cells that are recombinant vs. non-recombinant, and between cells that are *in vitro* and those present in a multicellular organism. Thus, it would impose both a search and examination burden to examine all four inventions together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups, and have acquired a separate status in the art because of their recognized divergent subject matter, for the reasons given above, restriction for examination purposes as indicated is proper.

Claim 1-15 and 20-30 link(s) inventions I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1-15 and 20-30.

Claims 16 and 31-38 link(s) inventions III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 16 and 31-38.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are

no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971).

See also MPEP § 804.01.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott D. Priebe

Scott D. Priebe, Ph.D.
Primary Examiner
Art Unit 1632